

expanding the stent within the region of interest; and
aspirating fluid and embolic debris from the region of interest;
wherein the step of aspirating fluid and embolic debris comprises the steps of
infusing fluid into the region of interest through an infusion lumen and one or more
infusion ports disposed on the aspiration catheter and suctioning the fluid and embolic
debris from the region of interest through one or more suction lumens in fluid
communication with a vacuum.

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Remarks

Applicants have carefully reviewed the office action dated September 18, 2002. Claims 1-21, 30, 36, and 42-54 are pending. Claims 1-20, 30, 36 and 42 are withdrawn from consideration. Claims 21 and 43-54 have been rejected. Applicants have cancelled claim 47-49 and have incorporated the elements of dependent claims 47 and 49 in independent claim 21. The specification has been amended to correct an informality.

Claim Rejections 35 U.S.C. § 112

Claim 48 was rejected under 35 U.S.C. § 112, second paragraph as being indefinite. Applicants have cancelled this claim, obviating the rejection.

Claim Rejections 35 U.S.C. § 102

Claims 21 and 47-54 were rejected under 35 U.S.C. 102(e) as being anticipated by Connors, III (U.S. Patent No. 6,295,989). Applicants respectfully traverse the rejection.

Connors, III does not anticipate amended independent claim 21 because it does not disclose each and every step of the claim. Specifically, Connors, III does not disclose

“wherein the step of aspirating fluid and embolic debris comprises the steps of infusing fluid into the region of interest through an infusion lumen and one or more infusion ports disposed on the aspiration catheter and suctioning the fluid and embolic debris from the region of interest through one or more suction lumens in fluid communication with a vacuum”. Connors, III does not disclose a catheter having more than one lumens capable of either infusion into the region of interest or aspiration from the region of interest. The only multi-lumen catheters disclosed by Connors, III have an occlusion or angioplasty balloon in fluid communication with a distal port of one of the lumens. Thus, the catheters disclosed by Connors, III are incapable of infusion and aspiration simultaneously. The method of Connors, III therefore relies on stopping flow in the common carotid artery, and thereby reversing flow in the internal carotid artery to flush the region of interest. See column 3, lines 12-16. It is therefore limited to treatment of the common carotid artery. In contrast, the method of the claimed invention does not rely on the particular features of any portion of the vascular system and is therefore suited to a wider number of locations in the vascular system.

Because the claimed invention of independent claim 21 is not anticipated by Connors, III, applicants submit that claim 21 is in condition for allowance. As claims 50-54 depend from claim 21 and contain additional elements, applicants submit that these claims are also in condition for allowance.

Claim Rejections 35 U.S.C. § 103

Claims 43-46 were rejected under 35 U.S.C. § 103(a) as being obvious over Connors, III in view of Imran (U.S. Patent No. 5,833,650). Applicants respectfully traverse the rejection.

As claims 43-46 depend from claim 21, which applicants submit is in condition for allowance, and contain additional elements, applicants submit that claims 43-46 are in condition for allowance.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "Version with markings to show changes made."

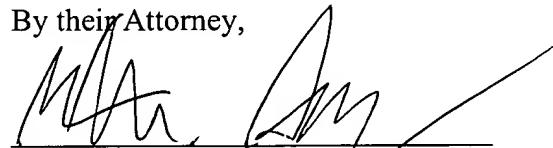
Reexamination and reconsideration are respectfully requested. It is respectfully submitted that the claims are now in condition for allowance, issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

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By their Attorney,

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Version with markings to show changes made.

In the Specification

Fig. 8 depicts another embodiment of the catheter system having stent deployment catheter 50 inserted through lumen 33 of aspiration catheter 30. Stent 55 is mounted on distal end 53 of catheter 50 and is operable through actuating mechanism 57 at the proximal end. In certain embodiments, stent 55 is made from shape-memory material, *e.g.*, nitinol. The stent is therefore self-expanding at body temperature and is simply released to actuate. Lumen 54 of catheter [20] 50 is adapted to receive guidewire 10, which has an arcuate distal end 12 to assist guidance through vessels. The aspiration catheter includes infusion ports 35 at distal end 32. Each infusion port communicates with infusion lumen 36 and proximal infusion port 37. Aspiration catheter 30 also includes aspiration lumens 38, which communicate with suction lumens 39 adapted for attachment to a vacuum at a proximal end. In certain embodiments, aspiration lumens 38 communicate with a single suction lumen 39.

In the Claims

21. (Twice Amended) A method for treatment of a vascular lesion, comprising the steps of:

introducing a guidewire into a vessel, the guidewire having an expandable occlusive member disposed on a distal end thereof;

advancing the guidewire to a region of interest and positioning the occlusive member distally of the region of interest;

advancing a catheter with an expandable stent over the guidewire and positioning the stent within the region of interest;

advancing an aspirating catheter over the guidewire and positioning the aspiration catheter proximal the [stent] region of interest;

expanding the occlusive member;

expanding the stent within the region of interest; and

aspirating fluid and embolic debris from the region of interest;

wherein the step of aspirating fluid and embolic debris comprises the steps of infusing fluid into the region of interest through an infusion lumen and one or more infusion ports disposed on the aspiration catheter and suctioning the fluid and embolic debris from the region of interest through one or more suction lumens in fluid communication with a vacuum.